

REASONS

In the Final Office Action mailed February 5, 2008, claims 1-10, 13-30, and 37-39 were rejected. The Advisory Action mailed May 30, 2008 maintained these rejections. It is respectfully submitted that there are clear errors with these rejections.

Rejections under 35 U.S.C. § 103

Claims 1-10, 13-30, and 37-39 stand rejected under 35 U.S.C. §103(a) as being unpatentable over WO 01/01893 to Marnay et al. ("the Marnay application"). As the PTO recognizes in MPEP § 2142:

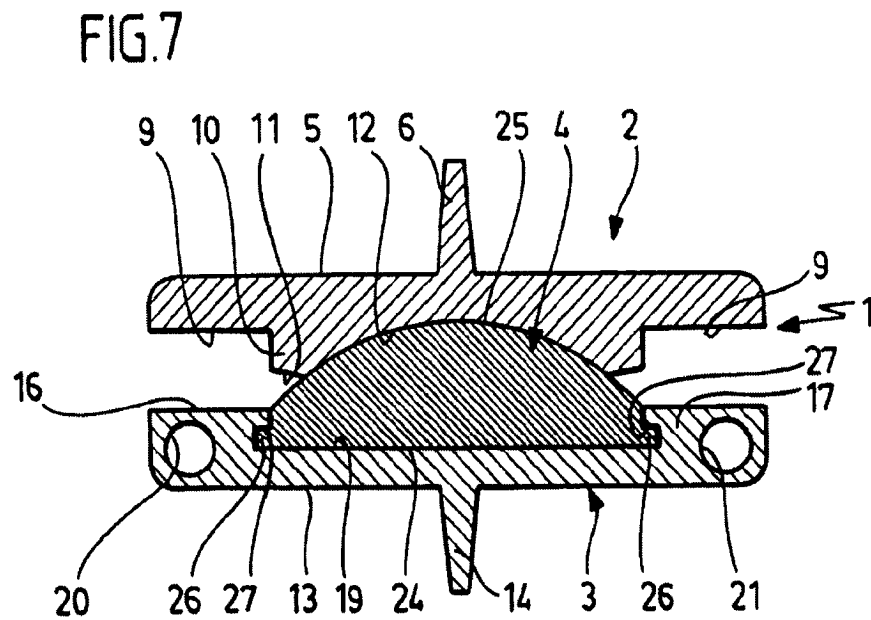
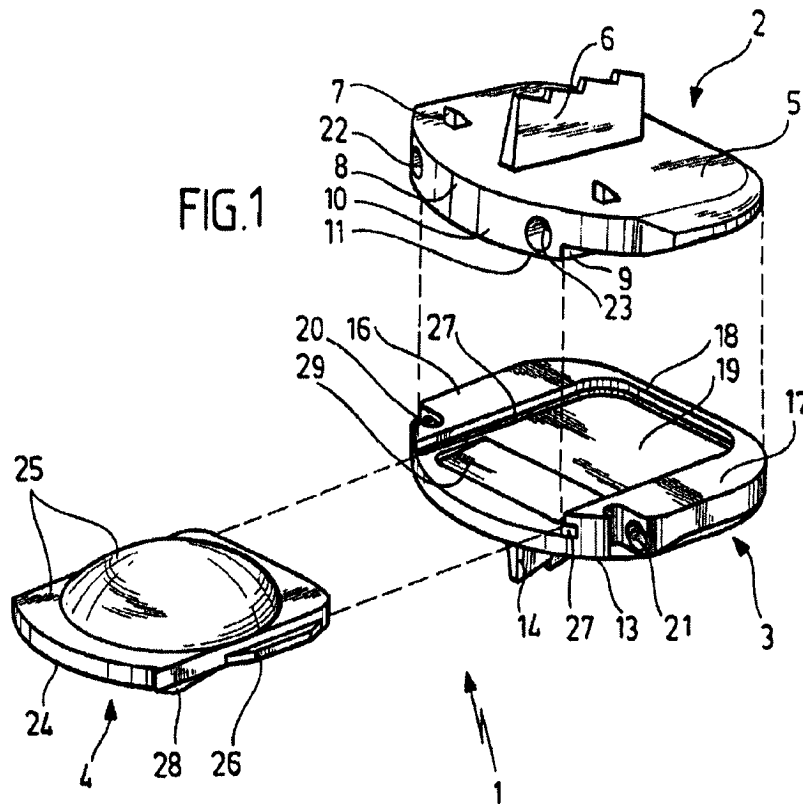
... The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the examiner does not produce a *prima facie* case, the applicant is under no obligation to submit evidence of nonobviousness...

There is clear error with these rejections because a *prima facie* case of obviousness has not been factually supported with respect to claims 1-10, 13-30, and 37-39.

First, with respect to independent claim 37, the Marnay application at least fails to disclose or suggest, "**A method for correcting spondylolisthesis** from an anterior approach, comprising: providing a prosthetic device having a first articular component with an **offset projection**, and a second articular component with an **offset recess** adapted to engage with the offset projection, and longitudinally inserting the first articular component into a first vertebra and longitudinally inserting the second articular component into a second vertebra, the second vertebra being adjacent to and in a **spondylosed relationship** with the first vertebra." (emphasis added). The Marnay application does not even mention spondylosed vertebrae or treating spondylolisthesis. Nor does the Marnay application disclose a device having articular components with an offset projection and recess. Accordingly, the Marnay application necessarily fails to disclose inserting articular components with an offset projection and recess between adjacent vertebrae in a spondylosed relationship to correct spondylolisthesis. Yet, the method of correcting spondylolisthesis as recited in claim 37 stands rejected solely over the Marnay application. There is obviously clear legal deficiency in this rejection.

As shown in Figures 1 and 7 reproduced below, the parts 2 and 3 of the Marnay application are configured to be substantially aligned, as indicated by the dotted lines. To that end, the spherically upwardly-curved topside 25 of the pivot insert 4 is centrally positioned and

configured to mate with the centrally positioned concave spherical indentation 12 of the upper part 2.



In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that “**a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, **it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.” *Id.* at 1741 (emphasis added).

As the typical treatment for spondylolisthesis at the time of the invention was fusion of the vertebrae, a reason must be provided for utilizing the implant of the Marnay application—which is configured to preserve motion between non-spondylosed vertebrae—for treating spondylolisthesis. Additionally, a reason for modifying the implant of Marnay to include an offset projection and recess for accommodating spondylosed vertebrae must be provided. No such reasons have been provided. The Office Action and Advisory Action assert that the catch-all “to address at least the need of satisfying varying requirements of patients having differing spinal anatomies sizes, conditions, deformities, etc.” is sufficient reason to utilize the implant of Marnay in treating spondylolisthesis and sufficient reason to modify the implant of the Marnay application to include an offset projection and recess for accommodating spondylosed vertebrae. Applicants respectfully disagree.

The Marnay application teaches away from the suggested modification of the implant. The Marnay application states that it is favorable for the spherical indentation or receptacle that receives the spherically curved top side of the insert to be “disposed in the central protrusion of the upper part.” Col. 3, ll. 13-14 (U.S. Patent No. 6,936,071) (emphasis added). Similarly, the Marnay application states that it is advantageous for the “central indentation of the lower part [to] form[] the receptacle for the pivot insert.” Col. 3, ll. 15-16 (U.S. Patent No. 6,936,071) (emphasis added). In this manner, the Marnay application highlights the importance of having the indentation and protrusion centrally located and teaches away from modifying the implant as suggested to include an offset projection and recess. The Supreme Court in *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007) maintained the long-standing principal that “when the

prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be non-obvious.” *KSR* at 1740.

The Marnay application simply does not disclose or suggest the limitations recited by claim 37, no reason has been provided for using the implant of the Marnay application to treat spondylolisthesis, and the Marnay application teaches away from modifying the implant as suggested. Accordingly, for at least these reasons there is clear error with the rejection of independent claim 37 over the Marnay application. Claims 38 and 39 depend from and further limit claim 37. Therefore, Applicants respectfully request that the §103 rejection of claims 37-39 over the Marnay application be withdrawn.

Similarly, with respect to independent claims 1 and 13, the Marnay application fails to disclose or suggest a motion-preserving implant having components with an offset projection and recess for accommodating spondylosed vertebrae as recited therein. As discussed above, the Marnay application does not even mention spondylosed vertebrae or a device for accommodating spondylosed vertebrae, nor does the implant of the Marnay application include components with an offset projection and recess. As no sufficient reason has been provided for modifying the Marnay application and the fact that the Marnay application teaches away from the proposed modification, there is clear error with the rejection of independent claims 1 and 13 over the Marnay application. Claims 2-10 depend from and further limit independent claim 1. Claims 14-30 depend from and further limit claim 13. Therefore, Applicants respectfully request that the §103 rejection of claims 1-10 and 13-30 over the Marnay application be withdrawn.

Conclusion

Applicants have shown clear legal deficiency and error in all of the Examiner's rejections. Therefore, it is respectfully requested that the rejections be withdrawn and prosecution be reopened.

Respectfully submitted,



Gregory P. Webb
Registration No. 59,859

Date: 7-24-08

HAYNES AND BOONE, LLP
Customer No. 46333
Telephone: (972) 739-8641
Facsimile: (214) 200-0853
File: P22461.00 / 31132.329
R-203368_1.DOC